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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/439,969 | 11/12/1999 | HITEN D. MADHANI | 2825.1013002 | 2363 |

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| EXAMINER |
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LEFFERS JR, GERALD G

11

| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/439,969

Applicant(s)

MADHANI, HITEN D.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 14-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 14, 16, 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicants' amendment, filed 10-1-01 as Paper No. 10, in which claims 9, 15 and 19 were amended. Claims 1-9, 11, 14-16, 18-19 are pending in the instant application with claims 1-8, 14, 16 and 18 withdrawn from consideration as being drawn towards different inventions.

Any rejection of record in Paper No. 8 that is not addressed in the instant action has been withdrawn. This action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, 15 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **For claims 9, 11 and 15, this rejection is maintained for reasons of record in Paper No. 8. Claim 19 has been included in the instant rejection because of amendment of the claim in Paper No. 10 to include specific gene embodiments (e.g. the specific genes claimed by claims 9 and 15).**

Response to Arguments

Applicant's arguments filed in Paper No. 10 have been fully considered but they are not persuasive. Applicants' response essentially argues: 1) the coding sequences for PGU1 and

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TOT10/YELO33W were publicly available at the time of filing at a web site sponsored by Stanford University, and 2) a contemporaneous paper by Blanco et al teaches the sequence of PGU1. These arguments are not persuasive on several grounds. A critical element of applicants' invention is the presence of regulatory sequences for each of the recited *genes* that are responsive to modulation of the MAPK filamentous pathway of yeast. Thus, it is not just the coding sequences of the recited genes that are critical to practicing the claimed methods. It is not at all clear that the information provided by the cited web site would have taught to one of skill in the art the necessary regulatory sequences required to practice the claimed invention (i.e. MAPK-responsive regulatory sequences). Such MAPK-responsive regulatory sequences would have to be determined by trial-and-error experimentation. Moreover, one of the requirements for biological materials under 37 §§ C.F.R. 1.801-1.809 is that the material be readily available to the public. There is no guarantee that the cited web sites will be available to the public for the entire term that would be granted upon issuance of a patent on the instant claims.

With regard to claim 19, it is not at all clear that the relevant coding and regulatory sequences were available to the public at the time of filing for each of the additional genes recited in the claim. Absent any evidence to the contrary regarding the availability to the public of such gene sequences, a biological deposit is required for each of the cited sequences.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. **This is a new rejection necessitated by applicants' amendment in Paper No. 10.**

Claim 19, as amended, is now directed to a series of specific genes that are purported to be modulated as part of the filamentation MAPK pathway in a fungus. The claim recites a method in which the gene encoding a particular MAPK pathway protein is transformed into a suitable host cell such that the host cell expresses the desired gene encoding a constituent of the MAPK pathway. The level of expression of the desired gene is compared between control cells and cells treated with a test compound. A difference in the level of expression of the desired gene for the test and control cells indicates that the test agent modulates the expression of the purported MAPK-pathway gene. Thus, a critical feature of applicants' invention is the presence of regulatory sequences that are part of the gene encoding the MAPK-pathway protein that is responsive to the filamentation MAPK pathway. The claims also encompass a potentially large genus of genes in that the claims are directed towards "a filamentation MAPK pathway in a fungus". Thus, a large number of potential genes (including MAPK responsive elements) from a large number of different fungi are encompassed by the rejected claim.

The cited passages from the specification provided in Paper No. 10 for support of the claimed method (page 3, first paragraph under REMARKS), wherein each of the regulatory/coding sequences recited in the amended claims is expressed as part of a method to identify modulators of the recited gene, does not provide literal support for the claimed method. Thus, the amendment to include each of the recited genes is considered to be NEW MATTER.

Moreover, the specification does not provide any description of the genes recited in claim 19 other than a name. It is not at all clear that each of the gene sequences, including MAPK-

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responsive regulatory elements, were described in the prior art such that one of skill in the art could envision nucleic acid constructs which are responsive to the MAPK pathway. Given the lack of description of any sequences in the specification, particularly of MAPK-responsive elements, the lack of description of such MAPK-responsive sequences in the prior art for the recited genes and the scope of potential genes from different fungal sources encompassed by the rejected claim, one of skill in the art would not have been able to envision a representative number of embodiments of genes sufficient to describe the entire genus. Therefore, one of skill in the art would reasonably have concluded applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, 15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by applicants' amendment of the claim in Paper No. 10.**

Each of the claims has the limitation "... transforming a suitable host cell. . . capable of expressing a gene when transformed with an expression vector comprising a nucleic acid encoding . . ." (examiner's emphasis added). The claims are vague and indefinite in that there is no explicit linkage of the nucleic acid to be expressed (i.e. a gene) with the recited gene (e.g. PGU1, etc.). It appears from reading the specification that it is essential to practicing the

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claimed method that the gene which is expressed be one of the recited genes. It would be remedial to explicitly link the gene which the cell is capable of expressing to the recited gene.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application, or relating to attachments to this office action, should be directed to the Patent Analyst Zeta Adams, whose telephone number is (703) 305-3291.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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ggl

December 16, 2001

DAVID GUZO
PRIMARY EXAMINER
David Guzo